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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,180	03/17/2004	Alan Brundle	EIS-6128 (1417G P 815)	3855
29200 7590 07/16/2007 BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER FRANTZ, JESSICA L	
			ART UNIT 3746	PAPER NUMBER
			MAIL DATE 07/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/802,180	Applicant(s) BRUNDLE ET AL.	
	Examiner Jessica L. Frantz	Art Unit 3746	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Action is responsive the Request for Continued Examination received 5/29/2007. Claims 1-34 have been cancelled and new claims 35-60 have been added. This Action is non-final.

Claim Objections

2. Claims 44 and 53 objected to because of the following informalities: both claims recite "a stepper motor responsive to the electrical current" but should be replaced with -
-a stepper motor responsive to the electrical current output-- in order to remain with previous terminology. Appropriate correction is required.
3. Claim 54 improperly depends from itself. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 35-43 recite the limitation "infusion pump stepper motor" and "stepper motor" in claim 35. There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 102

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
6. Claims 35, 36, 37, 39 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Butterfield 6,394,771. Butterfield teaches the invention as claimed including a method for driving an infusion pump motor 44, the method comprising the steps of determining a position in a pump cycle (via 62); determining a flow rate (see

column 8, lines 20-52); and adjusting an electrical current value for driving the infusion pump stepper motor in response, at least in part, to the position in the pump cycle and the flow rate as separate factors (via 60), wherein the steps of determining are accomplished at least 200 times per revolution of the stepper motor (column 7, lines 55-58) wherein the position in the pump cycle and an expected electrical current value are related to each other in a relational database and wherein the position in the pump cycle, the flow rate and an expected current value are stored in a database, and wherein the position in the pump cycle and the flow rate are related to the expected electrical current value (column 8, lines 20-28). Butterfield further teaches the step of modifying the electrical current value in response to input from a pressure sensor 66 (column 8, lines 31-43) and the step of micro-stepping the infusion pump motor (Abstract).

Claim Rejections - 35 USC § 103

7. Claims 44-49, 51-58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. 4,855,660 in view of Cartledge et al. 2003/0025396. Wright teaches the invention substantially as claimed including a system for controlling a stepper motor 18, a motor controller (microprocessor MPU, figure 3A) having an output responsive to a plurality of inputs (column 3, lines 3-11), the motor controller configured to output an electrical signal (electric signal sent from controller via various component to elements Q2-Q5) and to adjust the electrical signal; a current driver Q2-Q5 having an electrical current output responsive to the motor controller electrical signal; a stepper motor 18 responsive to the electrical current and at least one sensor

22, 20 having an output to the motor controller, wherein the motor controller is configured to determine a position of the motor with respect to the pump cycle (via sensor 20) or with respect to an output volume of the pump, and wherein a table of an expected electrical current values for a plurality of motor positions (lookup table not labeled, see column 3, lines 3-45) or output volumes are stored in a relational database (lookup table) accessible by the motor controller. It is discussed that in response to the electric signal received from the position sensor, the MPU retrieves information from a lookup table (relational database) in order to output an electric current signal which via various electric circuit component reaches the motor (column 3, lines 3-11 and figures 3A-3B). Wright further teaches the sensor is responsive to changes in the position of the stepper motor (a stepper motor position sensor). Wright further teaches that the controller and memory are within a microcontroller (column 3, lines 40-45). While Wright makes no explicit mention of the fact that the motor controller is responsive to changes in the age of tubing used for administering medication, the controller of Wright does include a memory as discussed above and is capable of storing the "age" of tubing used in a pumping application and it has been held that while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim. One would be prompted to

measure the age of the tubing on order to determine when it needs to be replaced.

Wright fails to teach an infusion pump that uses a stepping motor, the sensor includes a pressure sensor or a temperature sensor, a battery for operating the infusion pump, and that the motor controller and stepper motor is within the infusion pump. As taught by Cartledge, a stepping motor assembly 280 is successfully used to drive an infusion apparatus 100 and may additionally include a temperature sensor (sensor to interact with interface 2616) in order to determine a temperature of the fluid, a pressure sensor (sensor to interact with interface 2620) to determine a pressure condition of the fluid and a battery (not labeled, see paragraph [0067]) for powering the apparatus. It is noted that Wright, as previously discussed, taught various sensor's outputs are received by the MPU and in response to those outputs and a relational database the controller sends a signal to control the operation of the motor. By Wrights disclosure, it is understood that all sensors communicate with the MPU in the same way. Therefore, by combining the sensors of Cartledge, the modified invention teaches a table for an expected electrical current value based upon at least one of a temperature or backpressure of the fluid pumped. Cartledge also teaches the apparatus is combined into one structure including the controller 2600, pump 300, and motor 200 as shown in figure 12) which allows it to be portable (see paragraph [0068]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided a combined structure (pump, motor, and controller) allowing the infusion system to be portable, a battery for powering the system (also enabling portability), and

the pressure and temperature sensors to appropriately adjust the system in response to sensed parameters.

8. Claims 50 and 59 rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. 4,855,660 in view of Cartledge et al. 2003/0025396 as applied to claims 44-49, 51-58 and 60 above, and further in view of Harriman et al. 2003/0235409. The modified invention of Wright in view of Cartledge is discussed above but fails to teach the output of the motor controller is responsive to changes in the age of the motor. Harriman teaches modifying the output of the controller in response to the age of the infusion pump motor in order to ensure the proper motor performance (Paragraphs [0015] and [0016]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright in view of Cartledge with modifying the output of the controller in response to the age of the infusion pump motor in order to ensure the proper motor performance (Paragraphs [0015] and [0016]).

9. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butterfield 6,394,771 in view of Harriman et al. 2003/0235409. Butterfield teaches the invention as claimed and as discussed above but fails to teach the following claimed limitations as taught by Harriman: modifying the output of the controller in response to the age of the infusion pump motor (an elapsed time value) in order to ensure the proper motor performance (Paragraphs [0015] and [0016]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention Butterfield with modifying the output of the controller in response

to the age of the infusion pump motor in order to ensure the proper motor performance (Paragraphs [0015] and [0016]).

10. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butterfield 6,394,771 in view of Cartledge 2003/0225396. Butterfield teaches the invention as claimed but fails to teach the following claimed limitation as taught by Cartledge: modifying the electric current value provided to a stepping motor assembly 280 in response to input from a temperature sensor (sensor to interact with interface 2616) in order to determine a temperature of the fluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the teaching of Cartledge with those of Butterfield in order to determine a temperature of the fluid to appropriately adjust the system in response to a sensed temperature value.

11. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butterfield 6,394,771 in view of Maske et al. 6,208,107. Butterfield teaches the invention as claimed and as discussed above but fails to teach the following claimed limitations as taught by Maske: the step of half stepping the infusion pump motor. Maske teaches the step of half-stepping the motor in order to reduce excitation energy to approximately 29% of the full-step energy. (Column 3, lines 47-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Butterfield with the step of half stepping the motor in order to reduce excitation energy (Column 3, lines 47-51).

Response to Arguments

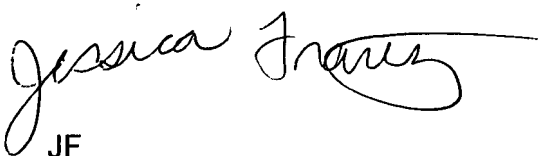
12. Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection and the cancellation of claims 1-34.

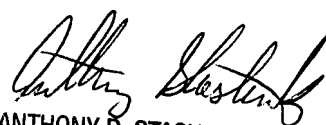
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Frantz whose telephone number is 571-272-5822. The examiner can normally be reached on Monday through Friday 8:30a.m. - 5:00p.m. E.S.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Stashick can be reached on 571-272-4561. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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